



SmartHerb

Innovating Botanical Health

Address: Chengnan Road, Huaxi Subdistrict, Changxing
County, Huzhou City, Zhejiang Province, 313100, China

Technical Data Sheet

Technical Data Sheet			
Product name	Lipo-vida™ Liposomal Berberine Hydrochloride 50%	Trade Brand	SmartHerb
AC Code	SH891331a	CAS number	633-65-8
Molecular formula	C ₂₀ H ₁₈ NO ₄ .HCl	Molecular weight	371.81
Item	Standard		Method of analysis
Appearance	Yellow powder		Visual
Assay	≥50%		HPLC
Ash	≤5%		Eur.Ph. <2.4.16>
Loss on drying	≤5%		Eur.Ph.7.0 [2.8.17]
Residual solvents			
Methanol	< 10 ppm		GC
Heavy metals			
Lead (Pb)	≤0.5 ppm		Eur.Ph.7.0
Cadmium (Cd)	≤1.0 ppm		Eur.Ph.7.0
Mercury (Hg)	≤0.1 ppm		Eur.Ph.7.0
Arsenic (As)	≤2 ppm		Eur.Ph.7.0
Microorganism			
Total Bacterial Count	≤1000 cfu/g		AOAC
Total Yeast and Mold Count	≤100 cfu/g		AOAC
Salmonella（10g）	Negative		AOAC
E. Coli（1g）	Negative		AOAC
Staphylococcus aureus（1g）	Negative		AOAC
Package	Paper drums with two plastic bags inside; 25 kg/drum		
Shelf life	24 months in original packaging under recommended storage conditions		
Storage	Store in a cool and dry place. Keep away from strong light and heat.		



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INGREDIENTS

An ingredient is defined in Directive 2000/13/EC on labelling: "ingredient means any substance including additives, used in the production or preparation of a foodstuff and still present in the finished product although possibly in a modified form" i.e. all raw materials to produce the goods.

Please list all ingredients:

Ingredients/material composition	%	Country of origin
Liposomal Berberine Hydrochloride	100%	China

ORIGIN

Country of origin of the product: China			
Is a manufacturing process available	☒ YES		☐ NO
Source of the product:	☐ Animal ☐ Synthetic	☒ Plant ☐ Biotechnological processing	☐ Mineral origin
please answer the following questions			
Ingredient Name: Liposomal Berberine Hydrochloride			
Starting material	Berberis aristata	Origin	China

GENETICALLY MODIFIED ORGANISMS-GMO

According to EU regulations EC/1829/2003 & EC/1830/2003

According to the EU regulations concerning the traceability and labelling of Genetically Modified Organisms (GMO), and the traceability of food products produced from GMO, we confirm that the product:		
Contains ingredient(s) from Maize and/or Soya origin	☐ YES	☒ NO
Contains no material which contains, consists of or is produced from authorized GMOs in proportion higher than 0,9%. This presence is adventitious or technically unavoidable	☒ YES	☐ NO
is GMO or contains or consists of GMOs	☐ YES	☒ NO
is produced from GMOs or contains ingredients produced from GMOs	☐ YES	☒ NO
Contains ingredient(s) from other potential GMO-risk raw material(s) (rice, beet, cotton ...)	☐ YES	☒ NO
If Yes, please specify: o ingredient: o vegetable origin: o geographic origin:		
Contains no material which contains, consists of or is produced from evaluated GMOs in proportion higher than 0,5%. This presence is adventitious or technically unavoidable	☒ YES	☐ NO
For information about processing aids, is produced or contains ingredient(s) produced with GMOs or Genetically Modified Microorganisms processing aids (bacteria, yeast... or derived from GMOs or GMMs (including enzymes)	☐ YES	☒ NO
If yes, please specify:		
We confirm that the ingredient supplied is compliant in all respects with the Regulations N°1829/2003/EC and	☒ YES	☐ NO



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N°1830/2003/EC where applicable		
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SUBSTANCES OR PRODUCTS CAUSING ALLERGIES OR INTOLERANCES

According to Regulation(EU)No.1169/2011 as regards of ingredients present in foodstuffs

Allergenic substances (Regulation EU 1169/2011 – Annex II)	Present in finished product	Present in the manufacturing site	Present on the same manufacturing line	Possible cross-contamination
Cereals containing gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridised strains)	NO	NO	NO	NO
Crustaceans and products thereof	NO	NO	NO	NO
Eggs and products thereof	NO	NO	NO	NO
Fish and shellfish-derived products (including gelatine)	NO	NO	NO	NO
Peanuts and products thereof	NO	NO	NO	NO
Soybeans and products thereof (including lecithin)	NO	NO	NO	NO
Milk and products thereof (including lactose)	NO	NO	NO	NO
Nuts (almond, hazelnut, walnut, cashew, pecan nut, Brazil nut, pistachio nut, macadamia nut,Macadamia Nut (including oil),Pine nuts (including oil))	NO	NO	NO	NO
Celery and products thereof	NO	NO	NO	NO
Mustard and products thereof	NO	NO	NO	NO
Sesame seeds and products thereof	NO	NO	NO	NO
Sulphur dioxide and sulphites (>10 mg/kg or 10 mg/L expressed as SO ₂)	NO	NO	NO	NO
Lupin and products thereof	NO	NO	NO	NO
Molluscs and products thereof	NO	NO	NO	NO
Buckwheat and products thereof	NO	NO	NO	NO
Cashew nutshell (including oil)	NO	NO	NO	NO
Bee pollen, propolis, royal jelly and products thereof	NO	NO	NO	NO
Latex	NO	NO	NO	NO
Lupines (lat. Lupinus) and products thereof	NO	NO	NO	NO
Peach (including oil)	NO	NO	NO	NO
Mango (including oil)	NO	NO	NO	NO
Pork and products thereof	NO	NO	NO	NO
Shellfish and similar products	NO	NO	NO	NO
Tomato and products thereof	NO	NO	NO	NO

NON IRRADIATION

According to UE Directive No.1999/2/CE

Has this raw material or one of its ingredients been irradiated or ionised	☐ YES	☒ NO
We confirm above non-irradiation statement is available	☒ YES	☐ NO



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NANOMATERIAL

According to Regulation(EU)No 1169/2011

Does this raw material contain or can be considered as engineered nanomaterial	☐ YES	☒ NO
Does this raw material have been made with nanotechnology?	☐ YES	☒ NO
Does the product contain nanotechnology as defined by the French decree no.2012-232?	☐ YES	☒ NO

WADA Anti-Doping Statement

Current WADA Prohibited List

Does the product contain any prohibited substances (hormones, anabolic agents, stimulants) listed on WADA Prohibited List?	☐ YES	☒ NO
Is there any risk of cross-contamination with WADA banned substances during production?	☐ YES	☒ NO

RESIDUAL SOLVENTS

According to UE Directive 2009/32, as amended, and CPMP/ICH/283/95Q3C

Does the raw material contain any residual solvent	☒ YES	☐ NO
If yes, please give: Solvent used during production: Solvent A (name and maximum residual level not specified in source document).		
Is the product in compliance with the UE Directive 2009/32	☒ YES	☐ NO
Is the product in compliance with the ICH guidelines	☒ YES	☐ NO

FOOD CERTIFICATE

Manufacturer's quality certificates:

☐ ISO 9001	☐ HACCP	☐ ISO 14001	☐ ISO 22000	☒ OTHER
Is the raw material Food Grade?	☐ YES	☒ NO		
Can the product be used in baby food(Regulation 2016/127/CE)?	☒ YES	☐ NO		
Does the product comply with the UE Regulation No231/2012 about additives?	☒ YES	☐ NO		
Is the product complying with a Pharmacopeia monography?	☐ YES	☒ NO		
Is the product complying with the UE Regulation No.1334/2008 about flavourings?	☒ YES	☐ NO		
Was the product used in the European food industry before May 1997?	☐ YES	☐ NO		
If no,could you provide an authorisation (according to Regulation 2015/2283/EC)?	☒ YES	☐ NO		
Are stability studies available?	☐ YES	☒ NO		

CONTAMINANTS

Is the product conforming to UE regulations No 2023/915 setting maximum levels for certain contaminants in foodstuffs,as amended?	☒ YES	☐ NO
Contaminants	Tested?	Result
Pesticides (multi-residue)?	YES	Complies with EC 396/2005; EP 07/2008;



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		USP <561>
Dioxins and dioxin like PCBs?	YES	Dioxins, Furans, Polychlorinated Biphenyls: Free
Heavy metals	YES	Total heavy metals ≤10 ppm; Pb ≤0.5 ppm; As ≤2 ppm; Hg ≤0.1 ppm; Cd ≤1.0 ppm
PAHs(PAH4)	YES	PAH4 ≤50 µg/kg
Benzo[a]pyrens?	YES	Benzo[a]pyrene ≤10 µg/kg
Mycotoxins (Aflatoxins, OTA)	YES	Aflatoxin B1 <5 ppb; Total aflatoxins <10 ppb; Ochratoxin A <15 ppb
3-MCPD	YES	Complies with EU No. 2020/1322
Doping like substances? http://list.wada-ama.org/	YES	No WADA-listed prohormones, stimulants, steroids or other prohibited substances

NUTRITIONAL VALUES

Nutritional Composition	☒ Per 100g	☐ Per serving
Energy(kJ/kcal)	1500 kJ	
Total Fat(g)	25	
Total Carbohydrate(g)	20	
Fibre(g)	0	
Protein(g)	0	
Salt(g)	0	
Vitamins:	0	
Minerals:	0	
Remarks: Nutrition Data are obtained by 3 rd party lab; tested on a yearly basis		

Safety Data Sheet (SDS)

Section 1 Identification of Substance			
Product Name	Liposomal Berberine Hydrochloride	CAS No.	633-65-8
Molecular Formula	C ₂₀ H ₁₈ NO ₄ .HCl	Molecular Weight	371.81 g/mol
Supplier / trade brand	SmartHerb Inc.	Address	Chengnan Road, Huaxi Subdistrict, Changxing County, Huzhou City, Zhejiang Province, 313100, China
Section 2 Hazards Identification Classification of the substance or mixture: No data available. GHS pictograms, signal word, hazard statements and precautionary statements: No data available. Other hazards which do not result in classification: No data available.			
Section 3 Composition, Information on Ingredients Molecular weight: 371.81 g/mol; Molecular formula: C ₂₀ H ₁₈ NO ₄ .HCl; CAS No.: 633-65-8. No components need to be disclosed according to the applicable regulations.			
Section 4 First Aid Measures General: No special measures required. Inhalation: Move victim to fresh air. If breathing is difficult, give oxygen; if not breathing, give artificial respiration and seek medical attention. Skin contact: Remove contaminated clothing, wash with soap and plenty of water, and consult a doctor. Eye contact: Rinse opened eye for several minutes under running water. After swallowing: If symptoms persist, consult a doctor.			
Section 5 Fire-Fighting Measures Suitable extinguishing media: Dry chemical, carbon dioxide or alcohol-resistant foam. Fire-fighters: Wear self-contained breathing apparatus if necessary.			



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Section 6 Accidental Release Measures

Personal precautions: Avoid dust formation and breathing mist/gas/vapour; avoid skin and eye contact; use personal protective equipment and ensure adequate ventilation.

Environmental precautions: Prevent further spillage/leakage where safe; do not allow material to enter drains or the environment.

Cleanup: Collect into suitable closed containers for disposal; remove ignition sources and use spark-proof tools/explosion-proof equipment where appropriate.

Section 7 Handling and Storage

Handling: Use in a well-ventilated place, wear suitable protective clothing, avoid skin/eye contact and dust/aerosol formation, and prevent electrostatic discharge.

Storage: Keep container tightly closed in a dry, cool, well-ventilated place, separate from food containers or incompatible materials.

Section 8 Exposure Controls/Personal Protection

Engineering controls: Ensure adequate ventilation and follow good industrial hygiene and safety practice.

Hand protection: Wear suitable gloves.

Eye protection: Wear tightly fitting safety goggles with side-shields conforming to EN 166 (EU) or NIOSH (US).

Skin protection: Wear fire/flammable-resistant and impervious clothing; gloves should satisfy EU Directive 89/686/EEC and EN 374.

Respiratory protection: If exposure limits are exceeded or irritation/other symptoms occur, use a full-face respirator.

Section 9 Physical and Chemical Properties

Physical state: Solid; Form: Powder; Colour: Yellow powder; Odour: Characteristic; Water solubility: Partially soluble.

Section 10 Stability and Reactivity

Reactivity, chemical stability, hazardous reactions, conditions to avoid, incompatible materials and hazardous decomposition products: No data available.

Section 11 Toxicological Information

Not toxic.

Section 12 Ecological Information

Material is non-toxic and biodegradable; no ecological effects stated.

Section 13 Disposal Considerations

Product: Dispose via a licensed chemical destruction plant or controlled incineration with flue-gas scrubbing. Do not contaminate water, foodstuffs, feed or seed and do not discharge to sewers.

Packaging: Triple-rinse (or equivalent) and recycle/recondition where possible, or render unusable and dispose in a sanitary landfill; controlled incineration may be used for combustible packaging.

Section 14 Transport Information

IATA: Not dangerous goods; IMDG: Not dangerous goods; ADR: Not dangerous goods; RID: Not dangerous goods; DOT: Not dangerous goods; TDG: Not dangerous goods.

Section 15 Regulatory Information

OSHA: Not classified into OSHA hazard categories. TSCA: All components are listed on the TSCA inventory. CERCLA: Spills are not subject to special reporting. RCRA: Not specified. SARA Title III: Not classified into any SARA categories. State regulatory information: Not specified. International regulatory information: Not known.

Section 16 Other Information

This SDS information applies only to the specified product unless otherwise stated. Users should make independent judgments regarding applicability; the source document states that the authors are not responsible for harm caused by use of the SDS.



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Flow Chart

